Misuse of Drugs (Ephedrine and Pseudoephedrine) Amendment Regulations 2004

Silvia Cartwright, Governor-General

Order in Council

At Wellington this 13th day of September 2004

Present:
The Right Hon Helen Clark presiding in Council

Pursuant to section 37 of the Misuse of Drugs Act 1975, Her Excellency the Governor-General, acting on the advice and with the consent of the Executive Council, makes the following regulations.

Contents

Regulations

1 Title

(1) These regulations are the Misuse of Drugs (Ephedrine and Pseudoephedrine) Amendment Regulations 2004.

(2) In these regulations, the Misuse of Drugs Regulations 1977[1] are called "the principal regulations".

[1] SR 1977/37

2 Commencement

These regulations come into force on 15 October 2004.

3 Interpretation

Regulation 2(1) of the principal regulations is amended by omitting the definition of **partially exempted drug**, and substituting the following definition:

"**partially exempted drug** means a controlled drug that is either of the following:

"(a) a controlled drug for the time being named or described in clauses 1 to 5 of Part III of the Third Schedule of the Act:

"(b) a preparation of pseudoephedrine that is—

"(i) named or described in clause 6 of Part III of the Third Schedule of the Act; or

"(ii) in a modified or sustained release formulation that delivers no more than 240 mg of pseudoephedrine in a 24-hour period".

4 Hospitals and other institutions

(1) Regulation 15 of the principal regulations is amended by omitting the words "or Part III".

(2) Regulation 15 of the principal regulations is amended by adding the words "and any partially exempted drug".

5 Supply and administration of controlled drugs without prescription

(1) Regulation 20(2)(a) of the principal regulations is amended by adding the words ", subject to subclause (3)".

(2) Regulation 20 of the principal regulations is amended by adding the following subclause:

"(3) For the purposes of subclause (2)(a), the following restrictions apply to the supply of any preparation of pseudoephedrine described in paragraph (b) of the definition of **partially exempted drug**:

"(a) the preparation may be sold by retail, or supplied in circumstances corresponding to retail sale, only in the circumstances set out in paragraphs (a) and (b) of the definition of **pharmacy-only medicine** in section 3 of the Medicines Act 1981; and

"(b) the package in which the preparation is sold or supplied must not contain more than 1.8 g of pseudoephedrine."

6 Labelling of containers

(1) Regulation 25 of the principal regulations is amended by revoking subclause (3), and substituting the following subclause:

"(3) Subclause (1) does not apply,—

"(a) in respect of ephedrine or pseudoephedrine, if—

"(i) the drug is enclosed in a primary container that complies with regulations 13(1)(a) and 16(1)(ab) of the Medicines Regulations 1984; and

"(ii) the larger container in which the strips of primary containers are contained complies with subclause (1) of this regulation; and

"(b) in respect of all other controlled drugs, if—

"(i) the drug is contained in a safety container within the meaning of regulation 2(1) of the Medicines Regulations 1984; and

"(ii) the labelling of the safety container complies with requirements of regulation 37(3) of those regulations."

(2) During the 6 months after these regulations come into force, no person is obliged to comply with regulation 25(3)(a) of the principal regulations in respect of ephedrine or pseudoephedrine if, and only if, the containers of those controlled drugs comply instead with the labelling requirements that applied to them immediately before ephedrine and pseudoephedrine became controlled drugs.

7 Custody of controlled drugs

Regulation 28(4) of the principal regulations is amended by adding the following paragraph:

"(e) a preparation of pseudoephedrine as described in paragraph (b) of the definition of **partially exempted drug**."

8 Notification of stock

Regulation 49A of the principal regulations is amended by omitting the words "or Part III of the Third Schedule to the Act", and substituting the words "of the Third Schedule of the Act, or in any partially exempted drug".

Diane Morcom,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 15 October 2004, amend the Misuse of Drugs Regulations 1977 (the "principal regulations") to give effect to the following 2 changes:

- to provide that the controlled drug pseudoephedrine, when contained in a slow-release formulation, is classified as a partially exempted drug for the purposes of the principal regulations, and therefore remains for sale without a prescription:
- to require that blister packs of medicines containing ephedrine or pseudoephedrine need only comply with the current requirements for the labelling to such blister packs, as long as the outer package is labelled appropriately under the principal regulations as well as under the Medicines Regulations 1984.

The background to these changes is that ephedrine and pseudoephedrine, which are currently contained in a number of prescription and pharmacy-only cold and influenza medicines, are to become Class C controlled drugs on the same day that these regulations come into force. The policy objective is to ensure that medicines containing ephedrine or pseudoephedrine should largely continue to be available to the public in the same way in which they

were available before ephedrine and pseudoephedrine were classified as controlled drugs.

A transitional period of 6 months is provided for. During the transitional period the new labelling requirements for medicines containing ephedrine and pseudoephedrine do not have to be complied with, as long as the medicines continue to be labelled as they were required to be labelled before these regulations came into force.

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These regulations are administered in the Ministry of Health.
